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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/091,897 | 03/06/2002 | Aneas Antoine | 1417G P 703 | 9171 |

7590 08/16/2004

Paul J. Nykaza
WALLENSTEIN & WAGNER, LTD
311 South Wacker Drive
53rd Floor
Chicago, IL 60606-6630

| EXAMINER |
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VIRDI, SUNDEEP

| ART UNIT | PAPER NUMBER |
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3763

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,897

Applicant(s)

ANTOINE, ANEAS

Examiner

Sundeep S Virdi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2 & 3.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: title has been omitted from the top of the first page of the specification. Additionally, the claim to foreign priority has not been made in the first sentence of the paragraph as required. Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a

nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

2. The abstract of the disclosure is objected to because Line 11 contains the language "said bore", which is impermissible legal phraseology. Line 12 contains the language "said stopper", which is also impermissible legal phraseology. Correction is required. See MPEP § 608.01(b).

3. Claim 11 objected to because of the following informalities: The word "comprise" on line 18 should be --comprises--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 is rendered vague and indefinite because the language utilized does not indicate whether the claim is dependent on claim 1 or if it is a separate independent claim. For examination purposes, examiner interprets this claim as being dependent on claim 1.

5. Claims 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4-7 are rendered vague and indefinite because the statement "said complementary means" on lines 24-25 was not claimed in claim 1. Claim 1 simply stated "stop means adapted to cooperate with complementary means". "Complementary means" was not claimed and therefore claim 4 falls as indefinite. Claims 5, 6 and 7 are rejected since they are dependant on claim 4.

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6. Claims 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9-10 are rendered vague and indefinite because it is unclear to the examiner what is meant by "it" in line 14 of claim 9 and line 16 of claim 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3, 6-8, 10 and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas ('623) in view of Pfeleiderer et al ('660).

With regards to claim 1, Aneas discloses a device for connection between a closed recipient and a container comprising a neck whose opening is closed by a stopper. Aneas discloses a base adapted to be mounted on a recipient (3) and comprising a sleeve (12) with an inner bore (12a). Aneas further discloses a plunger (15), adapted to slide in the bore and a stop means that will lock the plunger in a position of transfer (16).

With regards to claim 6, Aneas discloses hooks (16) that are provided with a nose.

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With regards to claim 8, Aneas discloses a second sleeve (22) disposed radially outside an interior sleeve (12).

With regards to claim 10, Aneas discloses a means for temporarily stopping the plunger in the disengaged position (column 2, lines 52-54). Aneas states that the invention is "in position fastened and locked on a first receptacle, and in the inactivated position of the plunger comprising the perforating means."

Additionally, with regards to claim 12, Aneas discloses a ready-to-use assembly comprising a closed recipient containing a product (2), with the recipient being provided with a neck (2a) whose opening is closed by a stopper (3), with a connection device (1) mounted on said recipient (see figs. 2-4).

However, Aneas does not disclose a needle with a non-circular cross section, a sleeve with a non-circular cross-section, such that the needle can slide in the sleeve without the possibility of rotation.

Pfleiderer et al teaches designing a spike with a non-circular cross-section in the same field of endeavor in order to prevent rotation of the spike (column 2, line 53).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle of Aneas with a non-circular cross-section as disclosed in Pfleiderer et al in order to prevent rotation of the needle. Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the sleeve surrounding the needle with a non-circular cross-section to prevent rotation.

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Claim 2 narrows the shape of the cross-section of the needle to an oval outer cross section with the sleeve having an oval cross-section. Pfeleiderer et al teaches using a spike with a non-circular cross section in the same field of endeavor in order to prevent the rotation of the spike (column 2, line 53).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an oval cross section since the reference discloses using a non-circular cross section and oval is a non-circular shape. Likewise, it would have been obvious to make the sleeve surrounding the needle oval in order to prevent rotation.

With regards to claim 3, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a polygonal outer cross-section with the sleeve's inner cross-section also being polygonal (see above discussion).

Additionally, the choice of a non-circular cross section in claims 1,2 and 3 would have been an obvious design choice. It would have been an obvious engineering design modification to change the shape of the cross section of the needle to a non-circular shape. Further, changing the shape of the needle does not affect the integrity of the invention.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas. Aneas does not disclose using ribs between two sleeves in order to form a rigid barrier to rotation of the sleeves with respect to each other.

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However, Aneas teaches using ribs connecting an inner sleeve (12) with a plunger (15) in order to form a rigid barrier for blocking rotation of the plunger with respect to the inner sleeve (column 4, lines 41-47).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the ribs disclosed in Aneas for the same purpose Aneas teaches (to prevent rotation between two radial surfaces) and modify the ribs for use between an inner and an outer sleeve to prevent rotation of the sleeves with respect to each other instead of between a plunger and sleeve.

9. Claims 4 and 5 are rejected under U.S.C. 103(a) as being unpatentable over Aneas in view of Pfleiderer et al and Martin (5,300,040). Aneas and Pfleiderer et al are discussed above in paragraph 7.

Aneas and Pfleiderer et al do not disclose a stop means comprising elastically deformable hooks with complementary means comprising bearing surfaces made on a flange in one piece with a needle, with the needle and flange together constituting a plunger as in claim 4 or a flange with openings for passage of hooks as in claim 5.

Martin teaches using hooks (62) with a complementary flange (52) that is in one piece with the needle and openings in the flange (column 4, lines 11-19) for passage of the hooks in the same field of endeavor, which could be adapted to be used as a stop means for the needle.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle of Aneas with a flange that has openings as taught in Martin in order to hold the needle in an engaged position.

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10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas in view of Pfeiderer et al and Thibault et al (WO 99/53886). Aneas and Pfeiderer et al are discussed above in paragraph 7.

Aneas and Pfeiderer et al do not disclose a stop means comprising at least one hollow made on the outer surface of the needle and at least one projection extending, from the inner radial surface of said sleeve, in the direction of a central axis of a bore adapted to be engaged with the hollow to maintain needle in position.

Thibault teaches using a hollow on the outer surface of a needle (see figure 10, hollow just above 476) that is engaged by a projection that extends from the inner radial surface of a sleeve (see figure 11, 478; see also page 14 lines 27-29).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Aneas by including a hollow in the needle and a projection on the inner surface of the sleeve in order to keep the needle in a disengaged position.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-3, 6-10 and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,5 and 6 of U.S. Patent No. 6,070,623 (Aneas) in view of 5,636,660 (Pfleiderer et al).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the additional elements claimed in the present application would be obvious to one of ordinary skill in the art in light of the teaching of the secondary reference Pfleiderer et al.

All the limitations of claims 1-3, 6-10 and 12 are present in claims 1, 2, 5 and 6 of Aneas as discussed above with the exception of a needle and sleeve with a non-circular cross section. Pfleiderer et al discloses the use of a spike with a non-circular cross section. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle of Aneas with a non-circular cross-section as disclosed in Pfleiderer et al in order to prevent rotation of the needle. Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the sleeve surrounding the needle with a non-circular cross-section to prevent rotation.

12. Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,5 and 6 of U.S. Patent No. 6,070,623 (Aneas) in view of WO 99/53886 (Thibault et al).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the additional elements claimed in the present application would be obvious to one of ordinary skill in the art in light of the teaching of the secondary reference Thibault et al.

All the limitations of claims 11 are present in claims 1, 2, 5 and 6 of Aneas as discussed above with the exception of at least one hollow made on the outer surface of a needle and at least one projection extending from the inner radial surface of the sleeve, in the direction of a central axis of a bore such that the projection is adapted to be engaged in the hollow of the needle in order to maintain the needle in a first stopped position. Thibault et al discloses the use of a spike with a non-circular cross section. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle of Aneas to incorporate a hollow on the outer surface of the needle and at least one projection extending from the inner radial surface of the sleeve, in the direction of a central axis of the bore, such that the projection is adapted to be engaged in the hollow of the needle in order to maintain the needle in a first stopped position.

13. Claims 4 and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,5 and 6 of U.S. Patent No. 6,070,623 (Aneas) in view of 5,300,040 (Martin).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the additional elements claimed in the present application

would be obvious to one of ordinary skill in the art in light of the teaching of the secondary reference Martin.

All the limitations of claims 4 and 5 are present in claims 1, 2, 5 and 6 of Aneas as discussed above with the exception of a stop means comprising elastically deformable hooks with complementary means comprising bearing surfaces made on a flange in one piece with a needle, with the needle and flange together constituting a plunger as in claim 4 or a flange with openings for passage of hooks as in claim 5.

Martin teaches using hooks (62) with a complementary flange (52) that is in one piece with the needle and openings in the flange (column 4, lines 11-19) for passage of the hooks in the same field of endeavor, which could be adapted to be used as a stop means for the needle.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle of Aneas with a flange that has openings as taught in Martin in order to hold the needle in an engaged position.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fowles et al ('068) discloses a vial connecting device that contains a first sleeve member that is mounted concentrically about a second sleeve member. Quick et al ('073) discloses a vial and syringe connector assembly that contains a flange as needle securing means. Knox et al ('029) discloses an additive device for a vial that contains rigid fins that hold a cannula in a rigid position against a cylindrical wall. Zbed ('209) discloses a sliding reconstitution device that contains a

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flange that secures the inner and outer sleeve of the device in a first inactivated position. Honda et al ('346) discloses a fluid container that contains a needle with arms that create a hollow around the needle which is adapted to be used with projections in a extending from the radial surface of a sleeve in order to hold the needle in position.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sundeep S Virdi whose telephone number is 703-305-0499. The examiner can normally be reached on M-F 9am-5:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nguyen
ANH TUAN T. NGUYEN
PRIMARY EXAMINER

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